

**UNITED STATES AIR FORCE
ARMSTRONG LABORATORY**

**Test and Evaluation of the Zoll
Medical Inc., PD2000 Cardiac
Monitor/Pacemaker/Defibrillator
System**

Edward W. Hade

Krug Life Sciences

Jacqueline D. Hale, Lieutenant Colonel, USAF

September 1997

DTIC QUALITY INSPECTED 3

*Approved for public release;
distribution is unlimited.*

Crew Systems Directorate
Crew Technology Division
2504 Gillingham Dr. STE 25
Brooks AFB, TX 78235-5104

19970918 104

NOTICES

This final technical report was submitted by personnel of the Systems Research Branch, Crew Technology Division, Armstrong Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency, contractor, or subcontractor thereof. The views and opinions of the authors expressed herein do not necessarily state or reflect those of the United States Government or any agency, contractor, or subcontractor thereof.

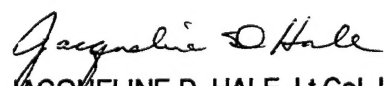
When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use or sell any patented invention that may in any way be related thereto.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

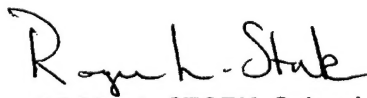
This report has been reviewed and is approved for publication.

Government agencies and their contractors registered with Defense Technical Information Center (DTIC) should direct requests for copies to: Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Ft. Belvoir, VA 22060-6218.

Non-Government agencies may purchase copies of this report from: National Technical Information Services (NTIS), 5285 Port Royal Road, Springfield, VA 22161-2103.



JACQUELINE D. HALE, Lt Col, USAF, NC
Chief, Aeromedical Research



ROGER L. STORK, Colonel, USAF, BSC
Chief, Crew Technology Division

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE September 1997	3. REPORT TYPE AND DATES COVERED Final, June 1996		
4. TITLE AND SUBTITLE Test and Evaluation of the Zoll Medical, Inc., PD2000 Cardiac Monitor/Pacemaker/Defibrillator System		5. FUNDING NUMBERS PE: 62202F PR: 7184 TA: 56 WU: 01		
6. AUTHOR(S) EDWARD W. HADE, (CIV) JACQUELINE D. HALE, LtCol				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Systems Research Branch 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104		8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Armstrong Laboratory (AFMC) Crew Systems Directorate Crew Technology Division 2504 Gillingham Dr. STE 25 Brooks AFB TX 78235-5104		10. SPONSORING/MONITORING AGENCY REPORT NUMBER AL/CF-TR-1997-0084		
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION AVAILABILITY STATEMENT Approved for public release; distribution unlimited.			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words) The Zoll PD2000 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, noninvasive temporary pacing and advisory capability. The Power Charger is designed to allow the PD2000 to be powered from a 120VAC/60 Hz source. Additionally, the PD2000 can receive power via a rechargeable 12 Volt Seal Lead-Acid battery pack.				
14. SUBJECT TERMS Zoll medical equipment Pacer airworthy aircraft Defibrillator Cardiac Monitor Conditionally approved PD2000			15. NUMBER OF PAGES 26	
17. SECURITY CLASSIFICATION OF REPORT UNCLASSIFIED			16. PRICE CODE	
18. SECURITY CLASSIFICATION OF THIS PAGE UNCLASSIFIED		19. SECURITY CLASSIFICATION OF ABSTRACT UNCLASSIFIED		20. LIMITATION OF ABSTRACT UL

TABLE OF CONTENTS

BACKGROUND	1
DESCRIPTION	1
PROCEDURES	3
INITIAL INSPECTION AND TEST PREPARATION.....	4
TEST SETUP.....	4
PERFORMANCE CHECK.....	5
VIBRATION.....	5
ELECTROMAGNETIC COMPATIBILITY	7
THERMAL/HUMIDITY	8
HYPOBARIC	9
AIRBORNE PERFORMANCE.....	9
EVALUATION RESULTS	10
INITIAL INSPECTION.....	10
VIBRATION.....	10
ELECTROMAGNETIC COMPATIBILITY	10
THERMAL/HUMIDITY	11
HYPOBARIC	11
AIRBORNE PERFORMANCE.....	11
SUMMARY	11
REFERENCES	13
APPENDIX	14

LIST OF FIGURES

Figure 1. Zoll PD 2000 System	3
Figure 2. Test Setup.....	5
Figure 3. MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17.....	6

ACKNOWLEDGMENTS

I would like to thank those who helped and provided advice during the evaluation of the PD 2000 System. I would particularly like to thank:

1Lt Kindra Edman
TSgt Butch Blake
TSgt Allen Jones
Mr Douglas Townsend

**TESTING AND EVALUATION OF THE
ZOLL MEDICAL, INC.,
PD 2000 CARDIAC MONITOR/
PACEMAKER/DEFIBRILLATOR SYSTEM**

BACKGROUND

Representatives of Zoll Medical, Inc. requested Aeromedical Research to evaluate and certify their PD 2000 System for use on board USAF aeromedical evacuation aircraft. Components of the PD 2000 System included the PD 2000 Cardiac Monitor/Pacemaker/Defibrillator, PD 4420 Battery Support System, and the Power Charger. All components of the PD 2000 System were tested for airworthiness. Throughout this report the term "PD 2000" refers to the PD 2000 Cardiac Monitor/Pacemaker/Defibrillator, while the term "PD 2000 System" refers to the PD 2000 Cardiac Monitor/Pacemaker/Defibrillator, the PD 4420 Battery Support System and the Power Charger (AC Power/Charger Module).

DESCRIPTION

The PD 2000 is a portable cardiac monitor, defibrillator and pacemaker that offers synchronized defibrillation, electrocardiogram monitoring, noninvasive temporary pacing, and advisory capability (Fig. 1). The Power Charger is designed to allow the PD 2000 to be powered from a 120 VAC/60 Hz or 120 VAC/400 Hz source. Additionally, the PD 2000 can receive power via a rechargeable sealed lead-acid battery pack located on the top face of the monitor. The duration of an individual battery's life varies as a function of the PD 2000's operating mode as well as the level and frequency of defibrillations. The specification for the battery life defines a range of 2.5 to 3.5 hours.

The defibrillator is capable of delivering up to 360 joules of energy. It may be used in synchronized mode for performance of synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The Zoll PD 2000 uses conventional paddles or disposable, pre-gelled, Multi-Function Electrodes for defibrillation.

The PD 2000 contains a non-fade monitor for observation of the patient's cardiac rhythm. The monitor displays the ECG in moving trace mode at 25 mm/sec for a period of 3.4 seconds. Also displayed on the monitor are:

- heart rate, derived from measuring R to R interval
- lead selections - I, II, III, Paddles, or Electrodes
- ECG size- 0.5, 1.0, 1.5, 2.0, 3.0 cm/mv
- pacemaker output in milliamps

- defibrillator output in joules
- other operational prompts, messages, and diagnostic codes

A strip chart recorder is provided to document events. The strip recorder normally operates in the delay mode for six seconds to insure capture of critical ECG information.

The PD 2000 is equipped with an advisory function to identify ventricular fibrillation and shockable ventricular tachycardias via an algorithm that analyzes the patient's ECG. A shockable rhythm is defined by the algorithm according to a specification for ventricular fibrillation and wide QRS-complex ventricular tachycardias with a rate greater than 150 beats per minute.

The PD 2000 will defibrillate, cardiovert and monitor using either defibrillation paddles or ZOLL Multi-Function Electrodes. The PD 2000 will also pace using either pacing electrodes or the Multi-Function Electrodes. Energy Select, Charge, and Discharge controls located on the paddles are not available when using Multi-Function Electrodes. You must use the controls located on the front panel and Multi-Function cable. The Advisory Analyze function cannot be activated unless Multi-Function Electrodes are installed and selected as the ECG monitoring lead.

The PD 2000 incorporates a noninvasive temporary pacing option with a control panel located on the top of the monitor. The pacer is a demand pacemaker consisting of a pulse generator and ECG sensing circuitry. The output current of the pacemaker is continuously variable up to 140 mA and the rate is continuously variable from 30-180 pulses per minute (ppm).

The following information defines the general specifications of the PD 2000 defibrillator. Size: 10.7 X 33.5 X 31.0 cm (4.2 X 13.2 X 12.2 in). Weight: 5.9 kgs (13 lbs) with PD 4400 Multi-Function Cable; 6.8 kgs (15 lbs) with paddles. Heart Rate Range: 0-300 BPM. Pacing Rate Range: 30-180 BPM. Pacing Current Range: 0-140 mA. Available Energy Range: 0-360 joules in 13 energy levels. Lead Selection: paddles, I, II, III. Printer speed: 25 mm/sec.

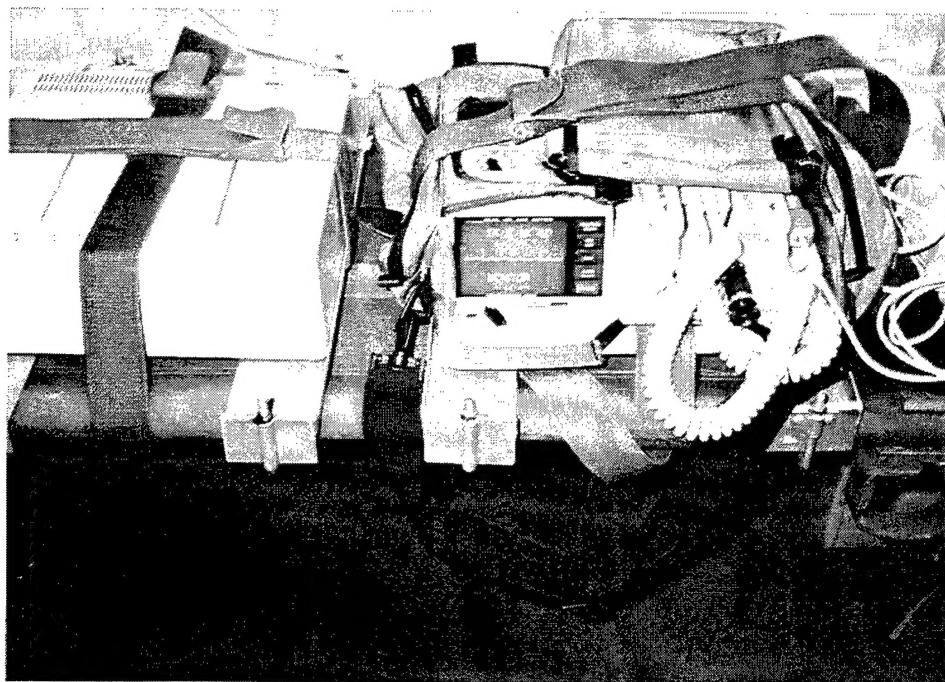


Figure 1. Zoll PD 2000 System

PROCEDURES

Test methods and performance criteria were derived from various military standards (1-3), nationally recognized performance guidelines (4), and manufacturer's literature (5). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (6). A test setup and performance check were developed specifically for this product to verify proper functioning of the equipment under various testing conditions.

The device was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)
4. Thermal/ Humidity, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity

- d. Hot Temperature Storage
- e. Cold Temperature Storage
- 5. Hypobaric
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient
- 6. Airborne Feasibility

INITIAL INSPECTION AND TEST PREPARATION

- a. The PD 2000 System was inspected for quality of workmanship, production techniques and possible damage incurred during shipment.
- b. The PD 2000 System was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (7), Electrical Shock Hazards, AFI 41-203 (8), and Equipment Management in Hospitals, AFI 41-201 (9). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.
- c. The PD 2000 System was examined to ensure it met basic requirements for good human factors design as outlined in MIL-STD 1472 (3).
- d. A test setup and performance check were developed to evaluate the PD 2000 System's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

One, of the following two analyzers, was connected to the ECG port on the monitor and provided the ECG waveform for the PD 2000 during the monitor portion of testing: the Lionheart Multiparameter Simulator or the Impulse 4000 Analyzer. The three ECG leads were attached to the corresponding color-coded receptacles on the analyzer. The Lionheart settings were the following: Lead Select, I/II; ECG amplitude, 1.0; and ECG BPM, beats per minute, 60. The Impulse selections were the following: ECG mode, Normal Sinus Group (NORM), and 60 beats per minute. The Impulse 4000 also analyzed the defibrillator portion of the PD 2000 when it operated in the DEFIB mode. Additionally, the Impulse 4000 analyzed the pacer option of the PD 2000, and its settings were the following: PACER mode, Internal 50 ohms load, PULSE and TEST. One sealed lead acid battery or the Power Charger provided power to the PD 2000. The PD 2000 was configured as follows: Lead Select, II; ECG size that allowed for the largest view of the waveform; pacer settings on 100 mA and 100 BPM when pacer was activated; SYNC mode selected (where applicable); when

in SYNC mode, ECG size control was adjusted such that the SYNC marker was positioned on the upper portion of the QRS complex.

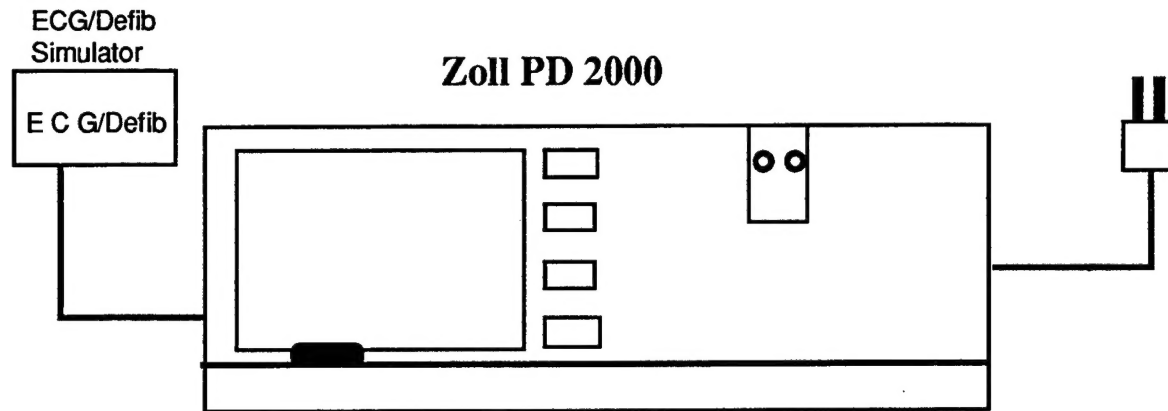


Figure 2. Test Setup

PERFORMANCE CHECK

As the PD 2000 monitored the ECG waveform, defibrillator energy levels were selected and the paddles subsequently discharged into the energy determining device. The performance check included discharging the paddles a number of times at both a high-energy level, 360 joules, and a low-energy level, 10 joules. Additionally, the baseline performance check includes testing synchronized defibrillation at an energy level of 50 joules. The ECG trace was used to visually confirm whether or not the defibrillator fired at the appropriate location on the waveform. The performance check concluded with the verification of the pacer output and recorder function. The Impulse 4000 monitored the pacer, ensuring the accuracy of the pacing frequency and amplitude.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (2). This testing involved a set of operational tests performed along each of the PD 2000 System's three axes - X, Y, and Z, with the PD 2000 System's components mounted on the NATO litter segment on the vibration table as they would be in the aircraft (Figure 3). They were subjected to vibration curves with similar levels and lengths as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

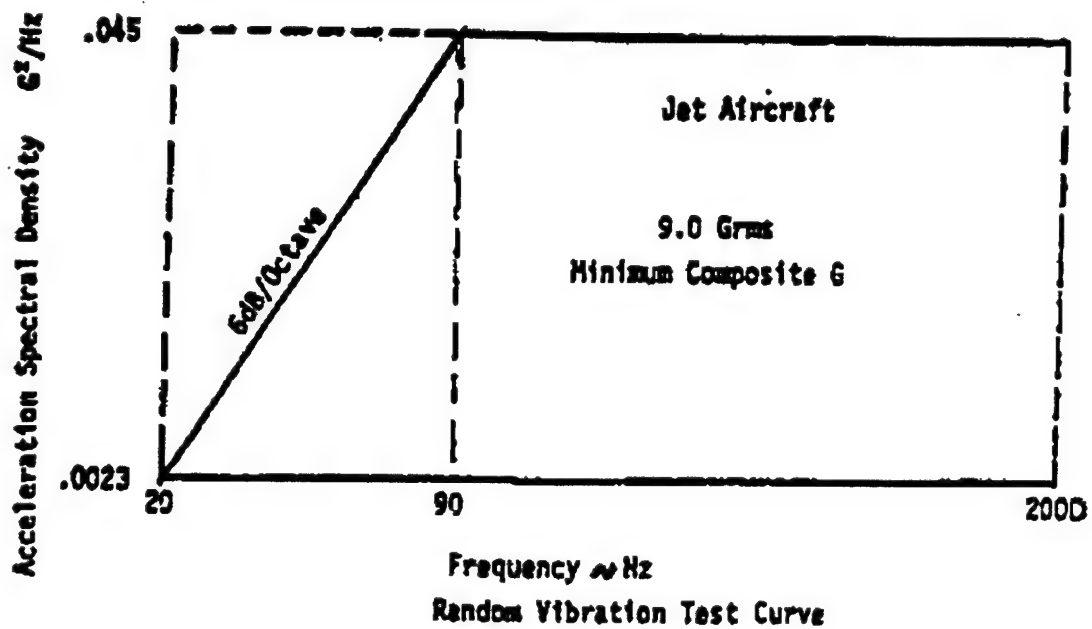
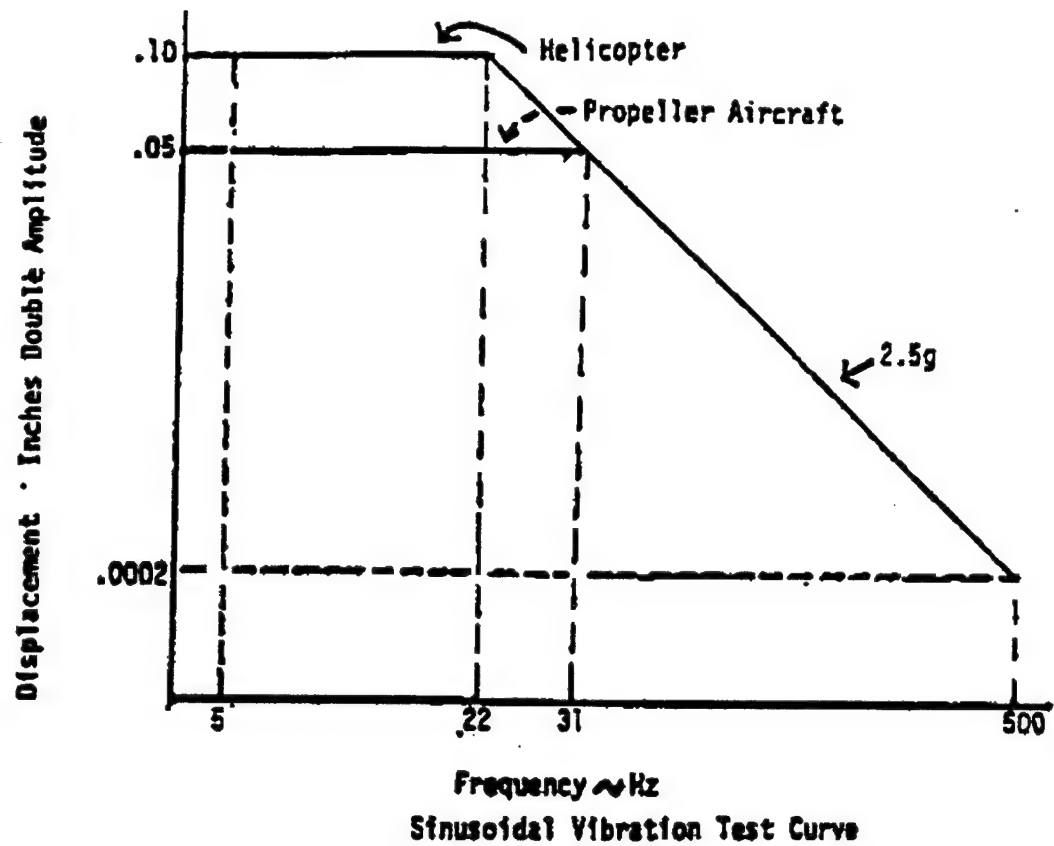


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor to assessing the effects of excessive electromagnetic emissions and their influence on aircraft navigation and communication equipment. Medical devices may be susceptible to fields generated by the aircraft equipment or other medical devices and malfunction in their presence.

The PD 2000 System was evaluated for compliance with MIL-STD-461D (1). Chomerics, Inc. of Woburn, Massachusetts performed the evaluation in their electromagnetic compatibility facility. WL/AAWA-2, Wright-Patterson AFB, evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test which measured the amount of EMI emitted by the equipment during its operation, was performed to verify that the device does not affect other pieces of equipment that may be susceptible to electromagnetic emissions (i.e., aircraft navigation and communication equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test which measured emissions generated by the medical device along its power supply lines, was performed to verify that operating the device using line power does not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test evaluated the device's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test determined the components' ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout a narrower portion of the frequency band, from 10 kHz to 200 MHz. This test determined whether "simulated

currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test evaluated the PD 2000 System's resistance to the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

During emissions testing, all options were operating for the duration of the test to create the "worst case" emissions scenario. These tests were accomplished in both pacing and monitoring modes. Throughout the testing, the Recorder (printer) ran continuously and the QRS beep sounded at maximum volume. For susceptibility testing, the PD 2000 System was operated individually in the pacing mode and in the monitoring mode. In the monitoring mode, the paddles were charged and discharged at intervals for two reasons. First, it allowed researchers to crudely determine if EMI would cause the equipment to defibrillate at times other than when the operator depressed the discharge buttons; and second, energy defibrillation levels and monitor function could be confirmed. Aeromedical Research personnel were unable to test the SYNC function because it would have required them to be subjected to dangerous levels of electromagnetic radiation. For both emissions and susceptibility testing, the PD 2000 System was tested for operation on 115VAC/60Hz, and internal batteries.

THERMAL/HUMIDITY

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance" (2). Extreme environmental conditions can have numerous incapacitating effects on medical equipment including, but not limited to, the following: changes in material characteristics and material dimensions, possible overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX. The PD 2000 System was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the PD 2000 System was monitored continuously, and a performance check was conducted every fifteen minutes. For storage tests, the PD 2000 System was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hrs
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hrs
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hrs
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hrs
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hrs

HYPOBARIC

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operation personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, TX.

a. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the PD 2000 System while ascending from ground level to 10,000 ft (maintaining altitude for one hour) and then descending back to ground, at rates of 5000 ft/min, while stopping at 2000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The PD 2000 System operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft (2,438 meters) altitude. Then, the chamber altitude was brought to 40,000 ft (12,192 meters) over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice with the decompressions occurring over seven and one seconds, respectively. The PD 2000 System was monitored throughout the series of decompressions, including performance checks each time the unit returned to ground. The simulator equipment remained outside the chamber. Connectors joining the Impulse analyzer and the PD 2000 and the power connector to the Power Charger were run through putty-sealed access ports in the chamber walls.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of

validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their actual environment, Aeromedical Research ensures that all pertinent patient care issues are adequately addressed by the test protocols. Ensuring safe and reliable operation of this medical equipment support device is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical flight nurse and aeromedical research technicians on board both a C-9 and C-130 aeromedical evacuation mission. The PD 2000 System was secured to the litter and evaluated throughout the flights by Aeromedical Research technicians as well as the other members of the aeromedical evacuation crew. Human factors characteristics, securing methods, and equipment setup times and locations were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

The Battery Support System experienced vibration failures and was sent back to Zoll Medical, Inc. for system redesign. The unit was eventually modified and returned to Armstrong Laboratory for vibration retest. Vibration retesting was conducted at the Aeromedical Research's vibration facility. The modified PD 4420 Battery Support System, Power Charger, and the PD 2000 tested with no failures.

ELECTROMAGNETIC COMPATIBILITY

While at the Wright-Patterson AFB EMI testing facilities, both the Power Charger and the PD 2000 experienced EMI failures. These units were sent back to Zoll Medical, Inc. for system redesign. To enhance EMI shielding qualities, copper foil tape (3M #1181) and a copper spray were applied to the inside plastic housing of both the Power Charger and the PD 2000 Pacemaker/Defibrillator.

These units were then EMI tested at Chomerics, Inc., Woburn, Massachusetts, under the direct supervision of an Armstrong Laboratory engineer, where they passed all phases of EMI testing in both the monitoring and pacing mode. However, because of potential differences in electromagnetic compatibility characteristics when pacing a human verses a simulator, Aeromedical Research is unable to confirm the airworthiness of the pacing mode. An in-depth research project is needed to study the

effects of pacing on human subjects within the aircraft and airborne environment in order to characterize the effects of the human's interaction with the system. ASC/ENAI, Wright-Patterson AFB, has currently certified the PD 2000 system for use in aeromedical evacuation on all Air Force aircraft while operating on 115VAC/60Hz or battery power.

THERMAL/HUMIDITY

The PD 2000 System operated satisfactorily during all five phases of testing.

HYPOBARIC

1. Cabin Pressure/Altitude: The PD 2000 System performed in accordance with manufacturer's specifications throughout testing.
2. Rapid Decompression: The PD 2000 System operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the PD 2000 System was performed on a C-9 aeromedical evacuation mission and C-130 aeromedical readiness mission. Evaluation confirmed that the unit would operate successfully during all phases of flight. The Vanner Inverter successfully supplied power to the Power Charger during the C-130 mission. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.

SUMMARY

Aeromedical Research found the Zoll Medical Inc. PD 2000 System to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60Hz or battery power with the recommendations and restrictions listed below. The PD 2000 System operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The pacer portion of the PD 2000 Pacemaker/Defibrillator is not approved for use in the aeromedical evacuation aircraft; however, the inactive pacer portion will survive the flight environment and be an available option for "off the aircraft" use. The following recommendations and operational restrictions accompany the airworthiness approval of the PD 2000 System:

- a. Add the following warning to the Operating Instructions and Service Manual:

WARNING: Restrictions for use on USAF aircraft: The pacing option is not to be operational at any time during flight. The Power Charger can only be used on 115VAC/60Hz. Ensure that there is a battery in the well while operating on 115VAC/60Hz.

b. Attach a warning label near the pacer control panel that reads, **"Do not operate pacer in flight."**

c. Attach a warning label on the Power Charger that reads, **"Do not operate on 115VAC / 400 Hz."**

d. Attach a warning label near the battery well that reads, **"Place battery in well before operating from 115VAC/60Hz."**

e. Inform Aircraft Commander that a cardiac monitor will be in use on board, and that they will be notified if defibrillation is to occur because of the possibility of electromagnetic interference with aircraft navigation and communication equipment.

REFERENCES

1. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
2. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
3. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
4. Emergency Care Research Institute (ECRI).
5. Zoll Medical Inc., PD 2000 System, Operator's Manuals.
6. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.
7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.
8. AFI 41-203, Electrical Shock Hazards.
9. AFI 41-201, Equipment Management in Hospitals.

APPENDIX

MANUFACTURER'S SPECIFICATIONS OF THE ZOLL MEDICAL, INC. PD 2000 SYSTEM

SPECIFICATIONS

General

Size	10.7 cm high x 33.5 cm wide x 31 cm long (4.2 in x 13.2 in x 12.2 in).
Weight	5.9 kg. (13 lbs.) with PD 4400 Multi-Function Cable; 6.8 kg. (15 lbs.) with paddles.
Power	Sealed lead acid battery; 2V/cell, 5 cells, wired in series.
Patient Safety	All patient connections are electrically isolated.
Environmental	Temperature: 0°C to 55°C (operating). -40°C to 75°C (storage and shipping). Humidity: 5% to 95% relative humidity, non-condensing.

Pacemaker

Type	VVI demand; asynchronous (fixed rate) when used without ECG leads.
Pulse Type	Rectilinear, constant current.
Pulse Duration	40 milliseconds.
Pulse Amplitude	Variable to 140 mA.
Pacing Rate	Variable from 30 to 180 ppm.
Output Protection	Fully defibrillator protected and isolated.

Defibrillator

Waveform	Damped sinusoid.
Output (delivered)	Selectable at 2, 3, 5, 7, 10, 20, 30, 50, 100, 150, 200, 300, 360 joules.
Energy Selection	Control on sternum paddle and unit front panel.
Charge Time	Less than 10 seconds. Depleted batteries will result in a longer defibrillator charge time.
Synchronized Mode	Synchronized defibrillator pulse to patient's R-wave. "SYNC" message displayed on monitor. Marker on monitor and on recorder paper identifies R-wave.
Charge Controls	Control on apex paddle and on front panel.
Paddles	Standard anterior/anterior adult and pediatric. Adult paddles slide off to expose pediatric paddles.
Defibrillation Electrodes	Pre-gelled ZOLL PD 2200 Multi-Function Electrodes, and Multi-Function Stat Padz packaged in pairs, can be used in the anterior/posterior or anterior/anterior position.
Defibrillation Advisory	Evaluates electrode connection and patient ECG to determine if defibrillation is required.

Monitor and Displays

Patient Connection	Via 3 lead ECG cable, paddles or electrodes. Selectable by front panel switch.
Input Protection	Fully defibrillator protected. Special circuit prevents distortion of ECG by pacer pulse.
Electrical Isolation and Shielding	Input protected against high-voltage defibrillator pulses and radio frequency interference.
Bandwidth	0.5-35 Hz (-3dB) standard- .05-35 Hz Diagnostic (optional).
Display Format	Non-fade, moving trace.
Screen Type	High resolution CRT display.

Screen Size	4.5 inches diagonally (56 mm x 86 mm, viewing area).
Sweep Speed	25 mm/sec.
Viewing Time	3.4 seconds.
Heart Rate	Digital display 0-300 bpm.
Pacer Output Current	Digital display 0-140 mA.
ECG Size	0.5, 1.0, 1.5, 2.0, 3.0 cm/mV - display on monitor.
Alarm On/Off Status	User selectable, High 60-280 bpm, Low, 20-100 bpm.

Recorder

Paper	Standard 40 mm thermal (grid width). 50 mm (paper width).
Speed	25 mm/sec.
Delay	6 seconds.
Annotations	Time, date, defib energy, heart rate, pacer output, QRS sync marker, ECG size, lead, alarm, defib test OK/Fail, analyze ECG, electrode pads off, analysis halted, noisy ECG, shock advised, no shock advised, ECG too large/adjust gain.
Print-out Modes	Manual or automatic - user configurable.
Control	Front panel and paddle.
Automatic Function	15 second recording initiated by alarm conditions and defibrillator discharge.

Battery Packs

Type	Rechargeable, sealed lead acid.
Weight	1 kg (2.2 lbs)
Voltage	2V/cell; 5 cells wired in series.

Recharge Time	16 hours for full recharge in ZOLL PD 4420 Battery Support System.
Operating Time	For a new, fully charged battery pack: 35 defibrillator discharges at maximum energy (360J), or 3.5 hours typical (2.5 hours minimum) of continuous monitoring, or 2.5 hours of continuous monitoring/pacing (PD 2000 only) at 60 mA, 80 beats/min.
Charger	Use ZOLL PD 4420 Battery Support System for recharging battery packs.